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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,311	10/11/2005	Hisao Kuroda	263364US0PCT	6731
22850 7590 10/06/2009 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER SRIVASTAVA, KAILASH C				
ART UNIT 1657		PAPER NUMBER		
NOTIFICATION DATE 10/06/2009		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/517,311

Applicant(s)

KURODA ET AL.

Examiner

Kailash C. Srivastava

Art Unit

1657

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-25 is/are pending in the application.
- 4a) Of the above claim(s) 8-9 and 14-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-7 and 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

1. Response and amendments filed 29 May 2009 in response to Office Action mailed 05 March 2009 is acknowledged and entered.

Withdrawn Objections/Rejections

2. In view of amendments and remarks filed 29 May 2009 the following objections/rejections in the Office Action mailed 05 March 2009 are hereby withdrawn:
 - Objection to specification for not perfecting the application priority data;
 - Indefiniteness rejection to Claims 1-3 under 35 U.S.C. § 112, second paragraph; and
 - Obviousness rejection to Claims 1-3 under 35 U.S.C. § 103(a) as obvious over combined teachings from Olías et al. (1990. Fatty Acid Hydroperoxide Lyase in Germinating Soybean Seedlings. Journal of Agriculture and Food Chemistry, Volume 38, Number 3, Pages 624-630) in view of Wikipedia http://en.wikipedia.org/wiki/Enzyme_assay Printed 3/1/2009 and <http://en.wikipedia.org/wiki/Malting> printed 3/2/2009).

Claims Status

3. Claims 1-4 have currently been cancelled.
4. Claims 5-25 have currently been added.
5. Claims 5-25 are pending.

Election /Restriction

6. In view of cancellation of Claims 1-4, Applicants' request to rejoin non-elected Claim 4, previously withdrawn in the Office Action mailed 05 March 2009 because of election of further prosecuting Claims 1-3 in the response filed 10 November 2008 is moot, but the subject matter of Claim 4 remains withdrawn because it still lacks unity of invention.
7. Newly submitted claims 8-9 and 14-25 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

8. This application now contains the following groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Restriction to one of the following inventions is required under 35 U.S.C. §121 and §372.

- ◆ Group A, consisting of claims 5-7 and 10-13, drawn to a method to screen for malt comprising determining the decrease in, or rate of decrease in, the concentration of fatty acid hydroperoxides (i.e., FAHPs) in a malt sample, said method further determining the amount of FAHP lyase (i.e., FAHPL) in said malt as a function of said decrease in the concentration of FAHPs and selecting a malt having a certain amount of FAHPL activity (i.e., ≤ 2 mU/g, or of ≤ 0.1 mU/g, or of ≤ 5 nkat/g).
- ◆ Group B, consisting of claims 8-9 and 14-22, drawn to a method to screen for malt comprising determining the increase in, or rate of increase in, the concentration of aldehydes resulting from the action of FAHPL on FAHPs in said malt and further determining the amount of FAHPL in said malt as a function of said increase, or rate of increase; calculating the activity of FAHPL based on the measured amount of aldehyde degradation product increase or rate of increase and identifying a malt having certain amount of FAHPL.
- ◆ Group C, consisting of claim 23, drawn to a method to screen for malt comprising measuring an amount of degradation products generated in a malt upon degradation by a FAHPL in said malt and further calculating the activity of FAHPL based on the measured amount of degradation products and identifying the malt having calculated FAHPL activity of $\leq 2\mu\text{U/g}$.
- ◆ Group D, consisting of claims 5 and 24, drawn to a method to screen for malt comprising determining the decrease in, or rate of decrease in, the concentration of FAHPs in a malt sample, further determining the amount of FAHPL in said malt as a function of said decrease, or rate of decrease in the concentration of FAHPs, identifying a malt and additionally producing a malt beverage from the malt identified.
- ◆ Group E, consisting of claims 14 and 25, drawn to a method to screen for malt comprising determining the increase in, or rate of increase in, the concentration of aldehydes resulting from the action of FAHPL on FAHPs in said malt and further

determining the amount of FAHPL in said malt as a function of said increase, or rate of increase, calculating the activity of FAHPL based on the measured amount of aldehyde degradation product increase or rate of increase, identifying a malt and additionally producing a malt beverage from the malt identified.

Inventions are Independent and Distinct

9. The inventions listed in Groups A-E above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The patent rules under 37 C.F.R. §1.475 for Unity of Invention (Paragraphs (a), (b) and (c)) are cited below:

§1.475 Unity of Invention before the International Searching Authority, the International Preliminary Examining Authority and during the National Stage

- (a) An International and National Stage Application shall relate to one invention only, or to a group of inventions so linked as to form a general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as whole, makes over the prior art.
- (b) An International or a National stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
 - (i) A product and a process specially adapted for the manufacture of said product; or
 - (ii) A product and process of use of said product; or
 - (iii) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
 - (iv) the said process; or
 - (v) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.
- (c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present. The groups of invention fall within category [(2), a product and a method of use of said product].

10. The inventions listed as Groups A-E do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

PCT Rule 13.2 does not provide for multiple compositions, or multiple methods of making a composition, or multiple methods of use of a composition within a single application. Thus, the first appearing composition is combined with a corresponding first method of making said composition (if applicable) and/ or use of said composition. However, the additional composition and method claims each constitute a separate inventive Group.

11. The special technical features of each of groups A-E inventions are different to each other because they each lead to a different effect through different steps. Furthermore, inventions in each of the Groups A-E do not share a common concept, e.g., invention of Group B has a technical feature of determining increase in the amount of rate of increase in the concentration of aldehydes; that is completely different in scope and concept from the Group A invention of determining a decrease, or rate of decrease in the concentration of FAHPs. The enzyme, i.e., FAHPL is the only common feature, however, determining the activity of said FAHPL is notoriously well known in the art as is already of record as pointed at Page 3, Lines 13-14 in the Election/Restriction requirement in the Office Action mailed 09 October 2008 (see for e.g., Olias et al (1990. Fatty Acid Hydroperoxide Lyase in Germinating Soybean Seedlings. Journal of Agriculture and Food Chemistry, Volume 38, Number 3, Pages 624-630)). Since no special technical feature exists between the inventions of groups A-E, there is no unity of invention.

The expression, "special Technical Feature" refers to those features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Thus, a feature found in the prior art can not be considered to be a special technical feature.

12. Since applicant has received an action on the merits for the originally presented invention, claims 5-7 and 10-13 – Group A, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 8-9 and 14-25 are withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. § 1.142(b) and M.P.E.P. §821.03.

13. Group A, Claims 5-7 and 10-13 are examined on merits.

Please note that Claims 5-7 and 10-13 are being examined only in as far as they read on the elected invention of "A method to screening a malt comprising determining the decrease in the concentration of fatty acid hydroperoxides in said sample, wherein said decrease in, or the rate of decrease in, the concentration of FAHP is indicative of FAHPL activity in said sample.

Claim Rejections - 35 U.S.C. §112

35 U.S.C. §112, First Paragraph

14. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 5-7 and 10-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for demonstrating fatty acid hydroperoxide lyase (FAHPL) activity by measuring the rate of decrease in the fatty acid hydroperoxides (i.e., FAHP) concentration, does not reasonably provide enablement for measuring said activity by a decrease in the concentration of said FAHP in a malt sample.

Enzyme activity is defined in terms of rate. Hence, measuring a decrease in substrate concentration cannot correspond to activity unless the time period during which the decrease occurs is known – $V = d[S]/dt$ (Sec Zeffren and Hall, 1973).

Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with Claims 5-7 and 10-12.

Claim Rejections - 35 U.S.C. §103

16. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

18. Claims 5-7 and 10-13 are rejected under 35 U.S.C. § 103(a) as obvious over combined teachings from Kohlmann et al (1999). Formation of lipxygenase-pathway-derived aldehydes in barley leaves upon methyl jasmonate treatment. European Journal of Biochemistry, Volume 260,

Pages 885-895) in view of Olias et al. (1990. Fatty Acid Hydroperoxide Lyase in Germinating Soybean Seedlings. Journal of Agriculture and Food Chemistry, Volume 38, Number 3, Pages 624-630) with evidence from Zeffren et al (The Study of Enzyme Mechanisms, Pages 54-55, 1973, New York, John Wiley & Sons) and further in view of Moake (1997 (or 2001-online) Make Your Own Malt. Brew Your Own Magazine, 1997 issue, Pages 1-5) with evidence from Wikipedia <http://en.wikipedia.org/wiki/Malting> printed 3/2/2009.

Claims 5-7 and 10-13 recite a method to screen malt by evaluating fatty acid hydroperoxide lyase (i.e., FAHPL) activity in said malt by measuring the decrease in, or rate of decrease in the concentration of fatty acid hydroperoxide (i.e., FAHP), wherein said decrease in, or rate of decrease in the concentration of FAHP is indicative of the activity of FAHPL. Further, the Claims are drawn to select a malt sample that has a FAHPL activity of ≤ 2 mU/g, or of ≤ 0.1 mU/g, or of ≤ 5 nkat/g.

Regarding Claims 5-7 and 10-13, Kohlmann et al., teach production of a variety of FAHPL mediated aldehydes in barley leaves. Said aldehydes, according to Kohlmann et al., are produced *in vivo* both endogenously and upon methyl jasmonate treatment (Abstract, Lines 5-8). Said aldehydes are produced because of the FAHPL activity on fatty acid hydroperoxides and were identified by GC-MS analysis (Abstract, Lines 5-6 and 8; Page 885, Column 2, Line 47; Page 886, Column 1, Lines 34-58 & Column 2, Lines 35-57; Page 889, Column 2, Lines 11-23 under Figure 2; Page 891, Column 1, Line 24 to Column 2, Line 18 under Figure 5; Page 892, Column 2, Lines 7-14 under Figure 6). Please note that in chemical kinetics measurement also applicable to enzyme catalyzed reactions, the activity of the enzyme can be measured by depletion of a reactant, $-d[S]/dt$, (i.e., FAHP in the instant case) or formation of a product, $d[P]/dt$, (i.e., production of aldehyde) (See Zeffren et al., Page 54, Line 13 to Page 55, Line 5). Please also note that if the activity of an enzyme is present in the plant leaves it will be present in fruits/ seeds or other plant parts as is well documented in the pertinent literature (See, e.g., Kohlmann et al., Page 886, Column 1, Lines 15-20).

Kohlmann et al., are silent regarding evaluating the FAHPL activity by measuring decrease in FAHP substrate measured as decrease in absorbance at 234nm and the malting or malt or reduction in the amounts of FAHP in selected malt.

Olias et al. teach evaluating the activity of FAHPL, wherein said FAHPL forms aldehydes hexanal and cis-3 hexanal during germination of soybean (Abstract Lines 1-9; Page

626, Column 1, Lines 3-25 below figure 2) by following decrease in absorbance of hydroperoxide substrate (i.e., FAHP) at 234nm (Page 626, Column 1, Lines 4-7 under Figure 2). Additionally, the aldehydes formed as the reaction products from the FAHPL activity determination were analyzed/identified by GC (Page 626, Column 1, Line 22 to Page 626, Column 2, Line 15 under Figure 2). Thus, Olias et al. teach determining FAHPL activity by both formation of product (i.e., aldehydes) and depletion of substrate (i.e., FAHP).

Moake teaches that malt is produced by the process of sprouting or germinating cereal grains and then stopping the germination by kilning (see Moake, Pages 1-5). During sprouting, the enzymes are produced that produce malt (see Wikipedia, Page 1, Lines 1-6).

One having ordinary skill in the art at the time of claimed invention would have been motivated to substitute the Olias et al. method of measuring FAHPL activity by a decrease in FAHP concentration for the method of measuring product in Kohlmann et al because Olias et al shows that the two assays are functionally equivalent consistent with the well known kinetics of substrate depletion or product formation as evidenced by Zeffren et al. Moake and Wikipedia establish that barley seeds and especially during malting are expected to inherently express FAHPL activity so that a person of ordinary skill in the art would reasonably expect to measure FAHPL activity in malted barley.

The prior art references cited *supra* are silent regarding selecting a malt having FAHPL activity of ≤ 2 mU/g, or of ≤ 0.1 mU/g, or of ≤ 5 nkat/g. However, the prior art teachings teach methods to evaluate the FAHPL activity in barley and other plant species and therefore a guidance for presence of some range of said activity in the plant sample evaluated; i.e., having FAHPL activity in a particular range. Thus, the prior art references give guidance for adjustment of particular conventional working conditions (e.g., choice of a variable, given concentration of a product or compound) and said adjustment is deemed merely a matter of judicious selection and routine optimization of a result-effective parameter that is well within the purview of the skilled artisan.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify Kohlmann et al's teachings with those of Olias et al., with support from Zeffren et al., Moake and Wikipedia; because Olias et al. teach determining FAHPL activity by either decrease in substrate concentration, or product formation, Zeffren et

al., teach that the enzyme activity is measured as a function of either the products formed, or substrate depletion, Moake remedies the deficiency regarding malt and malting and Wikipedia remedies the deficiency in Kohlmann et al's teachings of malting being an enzyme activation during sprouting.

From the teachings of the cited references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR §1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR §1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. For aforementioned reasons no claims are allowed. However, the claimed invention deems to be a "method of screening malt with least amount of FAHPL activity" so that beers produced from said malt will not go stale. Said concept may be allowable, if presented in an different form for Examiner's consideration, i.e., a method of selecting a malt with FAHPL activity below a certain level for the purpose of making a malt beverage. Additional literature search is always required to determine the patentability of amended Claims.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571)

272-0923. The examiner can normally be reached on Monday to Thursday from 7: A.M. to 5:30 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kailash C Srivastava/
Examiner, Art Unit 1657
(571) 272-0923

26 September 2009

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657